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ON

H.R. 5498

WMD Prevention and Preparedness Act of 2010

BEFORE THE

SUBCOMMITTEE ON EMERGING THREATS, CYBERSECURITY, AND SCIENCE AND TECHNOLOGY
COMMITTEE ON HOMELAND SECURITY
UNITED STATES HOUSE OF REPRESENTATIVES

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Washington, D.C.

Good afternoon, Chairperson Clarke and Subcommittee members.. I am Dr. Sara T. Beatrice, Assistant Commissioner of Health and Director of the New York City Public Health Laboratory (NYC PHL), a Bureau of the NYC Department of Health and Mental Hygiene (DOHMH). Thank you for the opportunity to testify on H.R. 5498, the "WMD Prevention and Preparedness Act of 2010."

The NYC PHL provides quality laboratory testing services that are needed by NYC DOHMH and its partner agencies, and our City's laboratory and healthcare community as they respond to clinical and environmental public health concerns. The NYC PHL has been a member of the Laboratory Response Network (LRN), an international network of laboratories able to respond quickly to public health threats and emergencies, since its inception in 1999. New York City has been a member of the BioWatch pathogen detection program since it was deployed in 2003, and is working with our federal partners in the assessment of new technologies and quality systems for this program. I am going to describe some of our challenges and experiences of the past decade in the hopes that it may be helpful to you as you consider legislation to improve the federal structure and support of bioterrorism preparedness and response.

New York City is a high threat jurisdiction. Our approach to bioterrorism preparedness is not theoretical; we have been attacked several times, and we are acutely aware that the City is a likely repeat target for terrorists. There will always be a need for significant bioterror response laboratory capacity and capability in the City to ensure our ability to rapidly and effectively respond to an event caused by the dissemination of a biological threat agent. In 1999, the NYC PHL received its first Centers for Disease Control and Prevention (CDC) grant to establish a biothreat response laboratory (BTRL). The first BTRL consisted of a single room situated in the middle of routine testing laboratories. Security was basic; there were padlocks for the evidence locker and a punch-code door lock at the entry. Later, the room access was upgraded to swipe card control and video surveillance was added. Reagents and resources were minimal; formal training was limited to one CDC-funded person attending a course on methods of agent identification at the CDC. In short, the NYC BTRL was a one-room space staffed by two laboratorians trained in standard safety methods for routine bacteriology work. There was only basic supporting infrastructure – there was no secure specimen receiving area, no secure computer database, no dedicated sample accessioning system, no standard report functions. Samples were delivered directly to the BTRL by first responders and tested for a collection of agents, and hand-written reports were sent to describe the results of the microbiological testing. All procedures were manual. There was no capacity for high throughput or Polymerase Chain Reaction (PCR) testing at that time. When the laboratory first became operational, the FBI submitted only approximately one specimen per month.

In October, 2001, on the same day that the index case of cutaneous anthrax was confirmed, law enforcement delivered a *Bacillus anthracis*-contaminated letter received at NBC by Tom Brokaw's staff. The BTRL sample load rapidly multiplied from a baseline of 10 samples in the previous year to hundreds of samples per day. Within days, the BTRL was transformed. Six tons of supplies were flown in from the CDC. Staffing

went from two to 75 laboratorians, including staff from CDC and the Department of Defense (DOD). Rapid, molecular testing was brought on board. Dedicated space was increased by almost twenty-fold and included 10 laboratories, evidence rooms, support and storage areas, and a command center. Databases and computers were brought in and standardized testing protocols were developed.

New York City has received funding from several sources for biothreat preparedness activities. CDC's Public Health Emergency Preparedness (PHEP) Cooperative Agreement provides funding to the NYC DOHMH, and a portion of this funding is allocated by the DOHMH to the PHL. However, PHEP funding is increasingly dedicated to specific initiatives, and is decreasing with each fiscal year. Public health agencies receiving PHEP funding were authorized to use this support to enhance responses not only to bioterrorism but to other intentional and unintentional incidents that could evolve into public health emergencies.

The Urban Areas Security Initiative (UASI) provides funding, through the Department of Homeland Security (DHS), to the City of New York. UASI funds are allocated annually by the City to programs, including the PHL. Procurement of an All-Hazards Receipt Facility (AHRF) was funded with $1.5 million from UASI. This facility was deployed to ensure that unknown samples could be screened for hazards (i.e.: chemical, radiological, etc.) before entering the laboratory. An AHRF is considered a safety necessity; however, many jurisdictions will not have adequate funding for this purpose.

PHEP, UASI and City funding has enabled the NYC BTRL to develop into its current iteration. The City is fortunate to have a Mayor who understands that public health is an integral part of biothreat preparedness and response, and Mayor Bloomberg has provided significant City tax levy monies for laboratory infrastructure. NYC dedicated $20 million of City capital funds to renovate the BTRL and Mycobacteriology laboratories after we were unsuccessful in getting federal capital funding for this essential project. This included a biosafety level 3 (BSL3) facility necessary for working with highly infectious organisms. Security upgrades were included as well. Physical barriers keep unauthorized vehicles from entering the PHL premises. There is 24-hour police presence in the building, which is enhanced when necessary, and extensive closed-circuit security system was installed in the building.

We believe that federal mandates for biosecurity enhancements must be federally funded. While the BTRL has moved far beyond a one room operation, there are upgrades and required maintenance to facilities, equipment, and instrumentation that we struggle to finance because external funding falls short, and the City and State dollars used to make up the difference are becoming increasingly scarce as well.

Today, many of the samples received by the BTRL are suspicious substances, such as unknown powders, that are found in envelopes or other packages. The samples are submitted by local (NYPD) and federal (FBI) law enforcement and originate from a variety of places. In 2009 and 2010 the laboratory has tested suspicious substances from many locations, including banks, financial businesses and organizations (37%),

governmental organizations (courts, transit, law enforcement agencies, 26%), embassies, consulates, diplomatic missions and the United Nations (26%), and hospitals, media organizations, and other businesses (11%). New York City is unique in that considerable portions of the NYC PHL budget are utilized to test samples which are collected from locations such as diplomatic missions and consulates that are considered "foreign soil".

Our federal and local partners, including in particular the NYPD, are responsible for responding to incidents involving suspicious substances and assigning a risk level to the event based on predetermined criteria. A decision is made whether testing is appropriate, and a priority is assigned to the sample. Many samples arrive at the PHL at the end of the work day and may require evening and weekend testing, and the overtime adds additional pressures on our budget. Maintaining a group of trained and competent on-call staff that can effectively respond 24/7 to a surge in sample volume is challenging.

If a suspicious substance were submitted and tested positive for the presence of a Select Agent, an immediate and significant environmental investigation would be launched, resulting in a surge of sample collection and confirmatory testing similar to that experienced during the 2001 anthrax event. We need to build and maintain a stable infrastructure of staffing, state-of-the-art testing methods, and a cache of reagents available to seamlessly move into a surge mode at any time. The NYC DOHMH, and the PHL in particular, recently challenged and proved the soundness of our system during the H1N1 outbreak of 2009. However, without adequate, consistent funding for staff, training, instrumentation, and reagents, this capacity will not be sustainable. We strongly support Section 2135 of H.R. 5498 which would provide funding for LRN activities, and we appreciate the bill's authors for recognizing this need.

NYC's involvement in the BioWatch program has been more substantial than in any other jurisdiction. Beginning in January 2003, NYC participated in the first deployment of BioWatch, a limited array of air collectors designed to detect the airborne release of select biological agents. The laboratory assays used in BioWatch were derived from those developed by Lawrence Livermore National Laboratory (LLNL) and CDC for the Biological Aerosol Sentry Information System (BASIS) program. During the initial BioWatch deployment in NYC, the BASIS mobile laboratory was deployed for approximately 2 weeks to NYC, assisting PHL staff to process and analyze BioWatch filters pending completion of the PHL BioWatch laboratory. When the BASIS laboratory staff left NYC, much of the testing equipment remained at the PHL to help initiate the establishment of this laboratory.

Soon thereafter, PHL recognized that additional support would be necessary for the BioWatch laboratory to become fully functional and self-sufficient. Instrumentation, reagents, informatics and staff, not accounted for when the program was established, would be needed. To assist PHL during this period, LLNL provided equipment and supplies directly from LLNL "push packs" (instrument and reagents required to do the testing) and dedicated staff were hired through the CDC.

PHL continued developing relationships with our federal partners during the next 12 months and embarked on the first of many pilot programs to enhance the capability and capacity of the NYC BioWatch laboratory. In February of 2004, LLNL provided DHS with a cost analysis to expand the laboratory capability that included additional instrumentation, implementation of sample tracking system, high-throughput sample processing and modified reagent contracts and formats. In March 2004, NYC staff was trained at LLNL in these new procedures with the goal to have the high-throughput laboratory in-place for the 2004 Republican National Convention (RNC). Based on the success of these initial programs, NYC, LLNL, DHS and CDC initiated 3 additional pilot programs beginning in 2004 to address IT enhancements, autonomous detection systems (APDS) and an improved platform for high-throughput testing (Luminex). The goal was to then provide other jurisdictions with these enhanced capabilities.

PHL, LLNL, CDC and DHS maintained close working relationships from 2004-2009 during the development, deployment and testing of the APDS program. In addition, BioWatch stakeholders throughout the City have been increasingly involved with DHS and CDC regarding the BioWatch mission, and we welcome continued involvement and collaboration. Efforts have been made in the past six months to improve communication and interaction between local, state and federal stakeholders who have invested much time and effort since 2003 in the BioWatch program.

One NYC experience illustrates the importance of improved communication. In 2003, NYC and federal partners began planning for special biosurveillance to be conducted during the 2004 Republican National Convention (RNC). Routine BioWatch testing was to be conducted by PHL, and federal partners were to collect National Security Special Event (NSSE) samples and test them at PHL. Weekly planning meetings with all partners were held for nearly a year to prepare for the event. The NYC DOHMH worked closely with local, state, and federal law enforcement agencies to develop a series of temporary security enhancements and procedures to ensure the safety of our staff, visitors, and information during the RNC event. Analytes were coded per mandate to ensure security, and testing was to be performed under "secret" conditions. Less than 48 hours prior to the Convention's start, our federal partners changed the reporting protocol. PHL was notified by the National Laboratory Program Manager that all NSSE data was to be reported directly to the National Laboratory Director. The National Laboratory Director was to notify the National Laboratory Program Manager. The National Laboratory Program Manager was to then report the results to our federal partner. Despite nearly a year of planning that involved all local and federal partners, the structure and processes were changed at the "eleventh hour". While the "new" reporting algorithm was not objectionable, the lack of communication and lack of transparency was counter-productive to the mission.

NYC's long involvement in the BioWatch program has resulted in some insight into the program. Based on our experience, we urge Congress to clearly define the roles and responsibilities of the entities involved – CDC, DHS, the contracting agent responsible for laboratory personnel, and the host laboratories. In addition, there is a need for a

central federal entity to guide consequence management planning in the event of a BioWatch Actionable Result (BAR).

We are concerned that DHS have adequate resources to support the additional responsibilities provided in this legislation. DHS is relatively new, and currently appears to be under-resourced. For example, the BioWatch program suffers from underfunding. The program was deployed hastily, and without an apparent understanding of what the true program costs would be. It is not clear that the correct funding algorithm for this program has yet been developed. Testing personnel, instruments, and reagents are federally funded. Local scientific and administrative oversight, laboratory support, security personnel and infrastructure, and overhead, such as space, waste disposal, equipment (e.g., autoclaves and biological safety cabinets), and office support are not federally funded, and represent a significant burden on laboratory budgets. Resources to build a quality system for the program are urgently needed. I am sure this Committee is well aware of the consequences of unreliable BioWatch results, and I want to thank the authors for recognizing this need in Section 2132 of H.R.5498 , which would provide additional financial support.

In "The World at Risk," the Commission for the Prevention of WMD Proliferation and Terrorism also recommended new government investments in biosafety and oversight of laboratories working with select agents. Comprehensive biodefense needs to address both intentional and accidental releases of biological threat agents. The NYC DOHMH is responsible for detecting and mitigating the impacts from any infectious disease outbreak that threatens public health, whether it is caused naturally, intentionally or accidentally. However, the NYC DOHMH does not have access to information that would enable it to mitigate vulnerabilities in certain laboratories before an accident occurs, or to be confident that spills and other accidents in NYC laboratories working with select agents would be reported promptly to the NYC DOHMH. Academic research laboratories are not regulated by New York City or New York State government, and through the Select Agent Act, the federal government provides the only oversight of biosecurity and biosafety within these facilities. The CDC releases only contact information to local and state public health agencies for laboratories regulated by the Select Agent Act. It is possible, for example, that a researcher could be exposed to a select agent through a laboratory accident, become ill, and expose others outside that laboratory. A second, limited SARS outbreak in 2004 resulted from just such a breakdown in biosafety in a Chinese laboratory. In the proposed bill, we hope that Sections 2105 and 2107 will provide for the sharing of information with public health departments that would be needed to mitigate and respond to select agent incidents in laboratories within their jurisdictions. As responsibility for Tier 1 and Select Agent Programs shifts from the Department of Health and Human Services to DHS, we encourage the federal government to take steps that address the public health requirements of jurisdictions within which select agent research takes place. Local and state public health agencies need to have access to detailed information related to the biological agents and biosafety programs at each laboratory regulated by the Select Agent Program.

The proposal in Section 2104 of H.R. 5498, to redefine a set of select agents as Tier 1 agents that require enhanced security, makes sense. However, the concordant enhanced biosecurity that will be required of facilities that handle these agents needs to be resourced appropriately and annually. Additional requirements will necessitate additional personnel. Currently, the NYC PHL Select Agents program has a Responsible Official (RO) and an Alternate Responsible Official (ARO); both are senior-level laboratorians that manage the program as one of their regular duties. Over time, increased duties for the RO and ARO in the form of increased responsibility for inspections and oversight, added requirements for conducting drills of increasing complexity, and requirements for detailed after-action reports have significantly increased workloads. However, there has been no concomitant increase in funding. Proposed additional requirements for handling select agents and Tier 1 agents need to be accompanied by an increase in funding for affected laboratories, including allocations for high-level personnel to oversee the program. Enhanced biosecurity for Tier 1 agents proposed in the legislation will be costly.

Public health laboratories are subject to regulation from a number of agencies. In addition to the LRN, the NYC PHL is a member of the Food Emergency Response Network (FERN), the environmental Laboratory response Network (eLRN), and the chemical Laboratory Response Network (LRN-c). The development of the Integrated Consortium of Laboratory Networks (ICLN), as provided in Section 2136 of the proposed Bill, promises to integrate and streamline regulations. We have yet to see benefits from the ICLN. We are still required at the public health laboratory level to input data into multiple, distinct data management systems, and the data is analyzed by each individual federal agency. The public health laboratory community has advocated for several years the use of a single laboratory data information management system, but this has not yet come to fruition. We support the participation of public health laboratories in the ICLN and look forward to a more focused and determined approach to integration. Organization through the ICLN could result in increased efficiency of resource use.

The NYC PHL is one player among many local, state and federal entities comprising the antiterrorism preparedness and response efforts in NYC. It is our duty to be prepared to provide the necessary surveillance, routine, and surge testing to support the emergency preparedness and response effort of the City. We need the support of our federal, state and local partners to be able to do this. Preparedness means not only meeting the threats of today, but also anticipating the threats of tomorrow. The building housing the NYC PHL was designed in the late 1950s and was opened nearly 45 years ago. An updated and upgraded facility is badly needed, and we are developing plans for a state-of-the-art facility that incorporates needed biosecurity and containment measures, as well as the technologies needed to detect emerging and re-emerging pathogens. However, the City faces challenges in funding construction of the new facility, particularly in the current economic climate. To optimally prepare for the future, the City would welcome the collaboration of the federal government in planning, funding and ensuring the further development of a state-of-the-art public health laboratory for highly-at-risk New Yorkers and for the Nation.

The New York City Department of Health and Mental Hygiene appreciates the opportunity to testify on the development and implementation of the important measures outlined within H.R. 5498, the "WMD Prevention and Preparedness Act of 2010." While I have limited my comments today to issues related to the NYC PHL, the City would like the opportunity to provide more detailed comments on the entire bill reflecting the concerns of all of our key emergency response agencies. The NYC DOHMH stands ready to assist the Committee, and our Nation, in any way possible, to develop and implement these critical initiatives. Again, thank you for the opportunity to testify, and I look forward to answering any questions you may have.

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